

AMENDMENT ONE (1)

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PURPOSE OF SOLICITATION AMENDMENT

The purpose of this amendment is to revise the Phase II budget for NIH/NCI Topic 375 Diagnostic Imaging for Cancer Immunotherapies and to respond to questions regarding NIH/NCI Topics 371 & 372.

The hour and date specified for receipt of Offers remains unchanged.

Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full effect.

Section 12 Component Instructions and Technical Topic Descriptions

National Cancer Institute (NCI), Topic 375 Diagnostic Imaging for Cancer Immunotherapies is revised as follows:

375 Diagnostic Imaging for Cancer Immunotherapies

Fast-Track proposals will be accepted.

Number of anticipated awards: 3-4

Budget (total costs, per award):

Phase I: up to \$300,000 for up to 9 months

Phase II: up to **\$2,000,000** for up to 2 years

PROPOSALS THAT EXCEED THE BUDGET OR PROJECT DURATION LISTED ABOVE MAY NOT BE FUNDED.

SPECIFIC TOPIC QUESTIONS

The Government's responses to questions received regarding this solicitation are as follows:

National Cancer Institute (NCI), Topic 371: Drugs to Exploit the Immune Response Generated by Radiation Therapy

Question 1: Would the Topic's prohibition on "Immune modulating agents that are already being tested in combination with radiation in clinical trials" also preclude reformulating agents for new mechanisms of action beyond the scope of their current "with-radiation" clinical trial(s)?

Answer 1: The intent of the Topic is to develop novel agents. It is not likely that a reformulated agent would be different enough to have a completely different mechanism of action. It will likely just be another mechanism of action that was not discussed or explored with the current study in the clinic. Unless the

reformulated agent has a very different composition and works via a totally different pathway/MOA, a proposal for a reformulated agent would not likely be successful under this Topic.

Question 2: Topic 371 states that it will not support “immune modulating agents that augment or negate immune functions in the absence of radiation.” My company has a compound which we know to enhance the effect of radiation in the treatment of cancers, as we have done some preliminary work on this. However, the compound by itself does have some endogenous immune enhancing properties. The compound is not on the market or FDA approved. It is a novel small molecule. Do you think this project would qualify under Topic 371?

Answer 2: The proposed agents would need to augment immune activation or inhibit immune suppression induced by radiation. Even the agents with some endogenous immune enhancing properties would be considered appropriate for Topic 371 as long as these agents can also modulate immune responses induced by radiation. So, the proposal would need to test the agents in combination with radiation and demonstrate immune modulation.

National Cancer Institute (NCI), Topic 372: Development and Validation of Non-Mouse Reagents to Enable Preclinical Development of Novel Therapeutics

Question 1: Can you please explain more what you are looking for in Topic 372? What do you consider to be "Non-Mouse Reagents?" Does this mean studies in mice are not allowed?

Answer 1: Non-mouse reagents refer to reagents that are specifically optimized for use in animal models other than mice. Thus, while mouse studies could be hypothetically used as a control, they are not the focus of this Topic.

End of Amendment 1